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Re-importation of Prescription Drugs
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Mr. Chairman, and Members of the Committee:

Thank you for inviting me to discuss re-importation of prescription drugs as a means of accessing safe, affordable prescription drugs from Canada and the current problems facing those individuals that are doing so [particularly our elders not currently covered under Medicare].

Today's healthcare market presents many challenges. None is more controversial than that of technology in the form of a "pill". Pharmaceutical spending has almost doubled in less than a decade. More often than ever, our policymakers and physician providers are being queried as to why it is that Americans, particularly the elderly, must pay many times more than their Canadian [and Mexican and European] counterparts for the same drug. As you know, over the past few years many of your constituents have been purchasing their medications from Canada. For these individuals, these medications are now affordable and even more importantly safe. From a pure medical standpoint, the most important part of a treatment plan that is intended to produce the best possible outcome for a patient, is the patients ability to comply with what 's prescribed by their provider/physician. Any medication that is not affordable and therefore not accessible, is neither safe nor effective for someone in need of it as part of their treatment plan.

Quality and Compliance

Many of the recent conversations around reimportation have focused on quality and safety issues. As providers of care, no one knows better than physicians and pharmacists how important quality is in the process of providing care. Quality can be defined in many ways, in this instance I want to discuss the importance of compliance for an individual/patient. When a physician/provider prescribes a medication as part of a treatment plan, they assume that the

individual will have access. Many do so because they [the provider] have used samples provided to them at no costs to give to their patients. So, when they have a patient that responds well to a particular medication provided as a sample, they do naturally what comes next in the process…write a prescription for the medication. Unfortunately, medications supplied as samples, in general, are the very ones that are not affordable.

Clearly as a provider network, our major concern is the ability of patients to comply with a given treatment plan. When a patient cannot afford their medications it is costly for all of us. Are we concerned about quality? Absolutely. And there is a quality issue and exist on this side of the border. When a patient cannot take their medications, they most definitely will consume services elsewhere in our system, such as the emergency room or by being admitted to the hospital. That simply is not rational. This is not about people that won't comply with a treatment plan, this about individuals that can't afford to purchase prescription drugs in the country they live in. Also, let's keep in mind that we are talking about Canada not some third world country. Having said this, these individuals are willing to take the risk associated with accessing their medications across the border. Many of them have told us that there is certainly no more risk in doing this than they are at by not taking their medications as prescribed or not at all.

Let's talk about quality and safety. I would ask you to reflect on when the last time was that you witnessed an armored vehicle delivering medications from manufacturer to the community pharmacy in this country. This is an extreme example, but I would like to make a point about safety under the guise of quality. Much propaganda has surfaced over reimportation of medications from other countries, particularly Canada. This attempt to frighten individuals that are already terrified of compromising their health by not being able to take their medications, creates a form of terrorism that is inexcusable. Some would have you believe that Canada's pharmaceutical supply is unsafe and of inferior quality. Ads placing pills side by side and questioning which one is the counterfeit drug, is a poor use of valuable resources and intended to produce fear. It does nothing to help address the problems associated with access.

Background on United Health Alliance and Medicine*Assist*

United Health Alliance is a nonprofit physician health system organization located in Southwestern Vermont. Our partners include a rural hospital, nursing home, home health agency and just over one hundred (120) community physicians. We serve residents of Vermont, New York and Massachusetts. Our mission is to promote a physician-driven organization whose principle services are to provide advocacy and leadership in the areas of care management, contracting, performance improvement and educational programs to maximize value for our physician-hospital membership and customers [patients]. Although we have committed to ten (10) guiding principles, none is more important to us than assisting the communities we serve at becoming the healthiest in the nation.

Approximately one year ago we found that although admirable, this objective was going to be very difficult to achieve given the circumstances that existed for some of our elderly. Very simply, they did not have access to affordable prescription drugs, therefore they were not able to comply with the treatment plans prescribed by their physicians. Although we had individuals that were seeking affordable medications via bus trips to Canada, we knew that this was not an option for the majority of the elderly in the communities we serve by virtue of their medical condition and/or their limited resources. One of our physicians came to us and requested our assistance at investigating how we could help a patient of his with breast cancer access her medications from Canada without having to get on a bus. Today that patient takes her medication because she can afford them. It cost her ninety (90) percent less in Canada. We compared the costs for 145 seniors for the first six months to see if what we had heard about the differences in pricing was in fact true. While these individuals would have had to pay just over $81,000 in the U.S., they paid approximately $22,000 for their medications in Canada (see Exhibit A). Our understanding is that there were no substitutions for the medications they were currently on. All medications accessed were for the treatment of chronic diseases such diabetes, heart disease and cancer. A price comparison of some of the more commonly prescribed medications for the treatment of these diseases has been provided along with this testimony. Although there is minor variation with some pricing in Canada, the savings are still significant and have been reported anywhere from thirty (30%) to (95%) percent (see Exhibit B). Although the majority of the individuals using Medicine*Assist* are the elderly on fixed incomes, with no prescription coverage, we are beginning to see individuals that have depleted their pharmacy benefits also attempting to access their medications from Canada. As we have conversations with employers located in the communities we serve about benefits and coverage for their employees we find many are concerned about how to continue the level of coverage they currently provide, particularly with the growth in their expenditures for prescription drugs. The implications are frightening for all of us.

Medicine*Assist* : Medicine*Assist* was created three (3) years ago to assist individuals in need of affordable prescription drugs access them from Canada. See website (**unitedhealthalliance.com**) and click on icon medcineassist for instructions and information on use. Maintenance drugs only and your personal physician must be involved. No membership fees. A Canadian licensed physician will review medical information and consult with your physician.

Points of Interest:

1. **Personal Re-importation:** A recent poll (06/02) identified over 1 million U.S. consumers using this as a means to access affordable prescription medications from Canadian pharmacies. Individuals from every State in the U.S. are currently using this mechanism. Some self-funded employers are investigating how they might help reduce health benefits cost by utilizing this

effort. Employers such as Marcus Moran, President of Aubuchon Hardware see this as moral obligation to their employees to reduce their [employees] costs of such benefits. It also means that coverage can be maintained or better yet, even be expanded.

2. **Compliance:** Physicians assume that when they prescribe a medication (write a script) that the patient will take their medication as prescribed. They don't have any interest in where you get it filled. This is not to say that they would not be concerned if they thought there was a safety or cost issue. They are concerned about compliance with regard to a prescribed treatment plan.

3. **FDA Site Visit:** The FDA completed a site visit/audit of the Medicine*Assist* I initiative on July 22, 2002 (almost 1 year ago). No notice to cease and desist was issued. Additional information can be provided to the Committee upon request.

Reasons for Price Differential in Canada and the U.S.

To put it in the simplest of terms: the Canadian government is the purchaser, therefore they have implemented controls over the costs. Next, they do not allow direct-to consumer advertising. My understanding is that this type of marketing is only allowed in the United States and New Zealand. Essentially our major mode of control is through the approval process by the FDA that essentially controls entry into the market, not pricing. In the U.S. with its non-universal coverage structure, cost containment is undertaken by a myriad of public and private decision-makers, each with their own agenda and objectives. The price differential is of course going to appear even greater when you compare a group that has no coverage and pays out of pocket. They have no purchasing power, because they have no coverage. This is particularly true for about one-third of the Medicare population.

Conclusion/Recommendations

Personal re-importation has for all intensive purposes, been implemented by the American consumer. It may or may not be a long-term solution, but it does provide an option, particularly for the elderly, until we can provide appropriate levels of coverage under Medicare without compromising current medical benefits. Long-term viability will depend on the development of a program that can be implemented not just signed into law [as evidence by MEDSA 2000]. Barriers to access are unacceptable. Reimportation of prescription drugs is working as a mechanism for access of affordable prescription drugs. Should the

current process be improved upon …absolutely! Should there be controls in place to monitor quality of those involved…absolutely!

Clearly, there is no simple answer with regard to the issues we are discussing. Barring any type of regulation of the pharmaceutical industry on this side of the border, personal reimportation from Canada under controlled circumstances can provide an interim solution for those in need of access to affordable prescription drugs. With the cooperation of the pharmaceutical industry, the FDA, the Canadian regulators and U. S. physicians/pharmacists a controlled demonstration project could achieve results that would prove beneficial for all the stakeholders until we can produce a better solution.

Notation:

1. Canada (as does other countries) has the equivalent of the FDA with regard to oversight.
2. The literature does not support fears about counterfeit drugs being dispensed from Canada.
3. Customer satisfaction and compliance for those currently using re-importation (Canada) appears high.
4. Physicians and pharmacists are engaged in the process. Compliance results in better outcomes and potential lower costs.

<u>FDA Oversight</u>

From the perspective of safety and oversight clearly the FDA [and other agencies] must be concerned as to how any initiative that would involve re-importation of prescription drugs would be maintained under their current charge. Although challenging, it can be done. With regard to Canada it would not be that difficult to do. Other countries **may** be more difficult to monitor and manage.

The following could/should be considered:

1. In order to maintain and provide an efficient means of oversight by the FDA, all participating pharmacies would be registered with the FDA. In order to do so, they would have to be accredited, much the same as the Joint Commission (JCAHO) accredits hospitals and other health institutions here in the United States. After meeting a set of quality standards the mail-order pharmacy would be awarded accreditation. They would also have to provide data/information to the FDA. Once all requirements are met, the FDA or another entity, would issue non-counterfeitable seals/emblems for these pharmacies to use when shipping packages into the US (through Custom). No seal, no entry in to the U.S.

Note: Prototype to be provided during testimony. I have been working with Flex Products, Inc. to produce a prototype seal using SecureShift™ technology. Flex Products is a world leader in the development of optically variable technology for counterfeit deterrence. Their Optically Variable Pigment (OVP) security technology is currently utilized by over 87 countries, including the US and the newly designed $10, $20, $50 and $100 bills. (Technical expertise from Flex Products, Inc. will be available for the Committee if they have detailed questions about the technology).

2. With regard to monitoring of the quality of drugs being shipped, a proxy with the country (Canada) could be established. There is no reason that we can not accept the standards that are equal or higher established by another country. No country should be allowed to participate that does not have at the very least a set of standards equal to ours.

3. The role of US and Canadian physicians and pharmacists could be worked out through the development of a cross-border association (licensure/registration and protocol development).

4. Private/Public partnerships should be developed in order to reduce the costs at the Federal level [while maintaining the oversight and input of the FDA].

<u>Major/Potential Barriers to Access from Canada:</u>

1. GlaxoSmithKlines recent actions to discontinue supplies to wholesalers and pharmacists in Canada for export. Although they accuse others of breaking the law, what they are doing although legal, is very unethical. Many individuals have complying with their treatment plans for almost three years and now they propose to take away their medications. All in the name of quality and safety...their answer… a prescription drug benefit under Medicare. With no costs controls put in place on the front end.

2. No one central clearinghouse to manage the process on this side of the border.

3. Personal reimportation is still considered illegal and therefore puts agencies such as the FDA in a very awkward position [actually impossible position until the law is changed]. They are charged with enforcing what currently exists and it's almost impossible to do so. Their recent threats to prosecute those of us that aid and that we may "be found civilly and criminally liable" was expected at some point, but is such an incredible waste of time and resources. This will serve to accomplish only one thing and that to hurt the very individuals that we profess to serve. Those individuals that are currently complying with their treatment plans. All of

this in the name of quality and safety. [a drug that is not accessible because it is not affordable is neither safe or effective]

Final Note:

In reality the economic model regarding sales for the pharmaceutical industry actually improves: 1) they now get inconsistent sales (unstable purchasing currently exist). Although the new sales would be a lower price, it would result in stability of purchasing and consistent compliance would result, which according to their own mission is their objective. 2) data reported by the Canadian pharmacies to the FDA could be very beneficial to research and development efforts and the development of a Medicare benefit.

This concludes my prepared remarks. Thank you again for this opportunity and I would be happy to try to address your questions